IRB Use Only
Approval Date: September 6, 2018
Expiration Date: **(Does Not Expire)**

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Elizabeth Kidd at

DESCRIPTION: You are invited to participate in a research study to determine which method of communication, phone or electronic, is better for increasing activity levels. You are qualify for this study because you are a survivor of endometrial cancer and you are interested in increasing your physical activity. If you choose to participate, Dr. Elizabeth Kidd, the Protocol Director and her research study staff will group you by length of time post-treatment (less than 1 year or 1-5 years) and type of treatment (surgery only or surgery with chemotherapy and/or radiation therapy). You will then be randomly assigned to phone call group (Arm 1) or electronic (text/email) group (Arm 2). You will have a fifty percent chance of being in the group that receives phone calls.

As a participant in this study you will be provided with a Fitbit device and need to wear it daily to record your physical activity. The Fitbit will record your daily steps and active minutes. The information about your average daily steps will be obtained from the Fitbit device on a weekly basis over the 9 months of the study and stored in a secure database. Only study personnel will have access to this secure database.

Phone or electronic reminders will occur every two weeks for the first two months and then during month 4 and 5. It will consist of a notification of the average daily steps for the last 2 weeks and goal setting future daily step counts.

Follow up visits during month 3, 6, and 9 will collect quality of life surveys (FACT-G), activity survey and health fitness measurements of height, weight, blood pressure, pulse, and waist circumference. You have the right to refuse to answer particular questions.

All required procedures are outlined in the study calendar:

	Pre-Study	Wk 2	Wk 4	Wk 6	Wk 8	Mo 3	Mo 4	Mo 5	Mo 6	Mo 9	Off Study[3]
Informed Consent	X										
Baseline Exercise Consultation	X										
Health Fitness Measurements[1]	X					X			X	X	X
Activity Survey	X					X			X	X	
Quality of life survey-FACT-G	X					X			X	X	X
Exercise Reminders[2]		X	X	X	X		X	X			

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1. Health fitness measurements include height, weight, blood pressure, pulse, and waist circumference
2. Phone call or electronic (text/email) intervention
3. Optional but recommended

RISKS AND BENEFITS: The risks associated with this study are possible injuries that may arise from increased physical activity and possible discomfort from wearing the Fitbit tracker**.** The benefits which may reasonably be expected to result from this study are receiving a Fitbit tracker and encouragement to increase physical activity. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: This research study is expected to take approximately 9 months from the time of enrollment. The study will take an extra 30 minutes of your time during your standard of care follow up at time of enrollment. It will take an extra 10 minutes at 3 month, 6 month, and 9 month follow ups. Phone calls or electronic intervention will take 5 minutes per time point which is every 2 weeks for the first 2 months, then at 4 and 5 months.

PAYMENTS: You will not receive as payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to determine the increase in activity level from the week 0-2 baseline to the week 22-26 by examining average weekly step counts measured by the Fitbit tracker. We will be comparing the group that receives electronic reminders versus phone reminders. You will be asked to answer specific questions and undergo standard of care follow-up visits. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Elizabeth Kidd at 875 Blake Wilbur Drive, Stanford, CA 94305

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What Personal Information Will Be Obtained, Used or Disclosed?

Your personal identifies and health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: name, medical record number, date of birth, phone number, home address, email address, details of cancer-related treatment, radiation treatment plan, brachytherapy dose, tumor pathology, tumor staging, side effects and toxicity related to cancer treatments, weight, height, waist circumference, blood pressure, heart rate, number of steps per day recorded by the Fitbit tracker, and quality of life information collected on surveys.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Elizabeth Kidd
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

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_____
Print Name of Adult Participant

WITHDRAWAL FROM STUDY

The Protocol Director may also withdraw you from the study, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Disease progression as outlined by the protocol.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Elizabeth Kidd at. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at You can also write to the Stanford IRB, Stanford University, Palo Alto, CA 94306.

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member, or other person who speaks both English and the participant's language)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*